REMARKS

The outstanding rejections independently allege that claims 6-16 lack novelty over each of Stoller et al, Juvelekian et al, and Doring. Applicants traverse each of those rejections as each improperly relies on applicants own teaching to support the rejection. In the absence of such teaching, the novelty rejection does not stand. Applicants request reconsideration and withdrawal of each of those rejections.

In clinical practice, no relationship has been found between low levels of AAT and fibromyalgia. Patients affected by low levels of AAT (which provokes abnormal pulmonary function) do not necessarily develop fibromyalgia; and low levels of AAT are not uniformly associated with fibromyalgia.

None of the outstanding rejections asserts that any of the references teach or suggest the contrary. Rather, the rejections all rely on applicants own discovery that fibromyalgia is occasionally coincident with reduced AAT levels. Indeed, the rejection based upon Juvelekian expressly relies applicants' own data (citing Table 1, page 7, of the instant application). The rejection relies on that data to assert a relationship between low AAT levels and fibromyalgia.

The reliance on applicants' own teaching is improper, and itself demonstrates that the cited references do not teach each and every step or limitation of the rejected claims.

The rejection points to no other art or evidence teaching or even suggesting a relationship between AAT levels and either the incidence or treatment of fibromyalgia. In fact, the teaching of Juvelekian itself is contrary to that premise. In Juvelekian (Table I, p.1747), genetic variants of AAT are tabulated according to, among other things, diseases known to be associated with each variant. Low levels

(abnormal function) of AAT are not anywhere shown to be related to fibromyalgia, or to pain.

The failure to identify such art or evidence outside applicants' own disclosure is fatal to the rejection.

Moreover, the rejection misconstrues applicants' own data, and relies upon a premise not supported by the data or applicants' discussion of it. The faulty premise is that low AAT levels are causally connected to fibromyalgia, and thus one would have known to administer supplemental AAT to treat fibromyalgia. The premise finds no support in either the cited art or in applicants' specification. Indeed, applicants' data and discussion run counter to it.

Applicants state that patients with fibromyalgia "were probably affected by a chronic inflammatory process of the soft tissues", which "could be the result of an abnormal imbalance between biological proinflammatory products ... and antiinflammatory products...." Specification, p. 7-8.

Applicants further state that "Hitherto unknown genetic, environmental, and possibly hormonal factors could be involved in the clinical expression of FM." Specification, p. 8.

Applicants' examples more firmly make the point. In applicants' Example 3, the development of fibromyalgia is not associated with the development of the clinical symptomatology of low levels of AAT. There, a patient with normal pulmonary function, i.e., without the classic symptomology of low AAT levels, exhibited fibromyalgia and responded favorably to the claimed method of treatment.

This suggests that normal levels of AAT do not prevent the development of fibromyalgia, while therapy with AAT administered to patients with fibromyalgia is

nonetheless capable of eliciting clear improvement in the clinical evolution of the disease.

Applicants disclosure fails to teach or suggest a relationship such as the rejection relies upon, and the reliance on applicants' data to conclude that low AAT levels necessarily are associated with the onset of fibromyalgia is not only inappropriate, but misplaced.

None of the cited references has been shown to teach the use or effectiveness of AAT therapy in the treatment of fibromyalgia. The claims require the administration of AAT to patients diagnosed with fibromyalgia. As none of the references teaches a method for the treatment of fibromyalgia involving the administration of AAT, nor any relationship between AAT therapy and fibromyalgia, none of the references teaches a method involving all the steps recited in the claims. Thus, none of the cited references anticipates the claims.

In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

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Date: 8/2/06

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